PSS38
PAYER NEEDS IN EMERGING MARKETS: HOW SHOULD THESE NEEDS BE INCLUDED IN DERMATOLOGY DRUG DEVELOPMENT PLANS?
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OBJECTIVES: Health technology assessment (HTA) is a rapidly growing field, and countries in the Asia-Pacific and Latin America regions are in the process of developing economic assessment guidelines for pharmaceutical products. The objective of this evaluation was to determine how emerging market payer needs should be included in drug development plans. **METHODS:** Payer needs were evaluated for Brazil, China, India, Japan, and South Korea. Dermatology was chosen as the example therapy area, because Asia and South America are large and important markets for dermatology. Based on the results, a process map was developed outlining the steps and timeline for including country-specific needs in drug development plans. Additionally, key survey questions were developed for country-specific input. **RESULTS:** Brazil has a formal HTA body, CONITEC (Comissao Nacional de Incorporaca de Technologias), which makes appraisal decisions based on cost-effectiveness and budget impact analysis. Similarly, South Korea has a formal process based on cost-effectiveness or cost minimization analysis. India is primarily a self-pay market for dermatology but has proposed pharmacoeconomic guidelines (ISPOR 2013) for formal assessments. In China, health economic (HE) data are required in negotiations for high-price products at the provincial or city level but not at the central level. Japan has no formal HE data requirements. Topics for key country survey questions included disease prevalence, economic burden, treatment guidelines, drug listing procedures, HTA decisions for current therapy, and key comparators. **CONCLUSIONS:** Timely inclusion of payer needs in the drug development process is critical for market access with emerging markets.

URINARY/KIDNEY DISORDERS – Clinical Outcomes Studies

PUK1
TREATMENT PATTERNS OF URINARY INCONTINENCE IN THE PRESENCE OF COMORBIDITIES
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OBJECTIVES: Urinary incontinence (UI) is an undertreated condition. We examined the likelihood of receiving UI treatment in subjects having UI alone and UI along with different comorbidities. **METHODS:** This was a retrospective cross-sectional study of a 10% random sample of IMS LifeLink data from 2001-2011. Subjects were >= 18 years of age and continuously enrolled 6 months pre and post their first index diagnosis. UI subjects had at least two outpatient or one outpatient and one inpatient claims at least 7 days apart. Co-morbidities were observed in the pre- and post-index periods. Five mutually exclusive comorbidity groups were then formed: UI alone, UI with multiple sclerosis or Parkinson's diseases or stroke, UI with diabetes or cardiovascular diseases, UI with arthritis or respiratory diseases or inflammatory bowel disease or dementia, or UI with any other co-morbidities. Treatment (Pharmacotherapy or behavioral therapy for UI) was observed 15 days pre- and 6 months post-index UI diagnosis. Logistic regression adjusted for region, age and Charlson comorbidity score was used to contrast these comorbidity groups on the likelihood of receiving treatment for UI. **RESULTS:** There were 4,374 (28.15 %) subjects with UI who received treatment, and 11,162 (71.85 %) with UI and did not receive treatment. The odds of receiving treatment was only influenced by those with multiple sclerosis, Parkinson's diseases or stroke subjects for those with (aOR = 1.46, p<0.001). **CONCLUSIONS:** Current guidelines recommend treatment for UI in the presence of multiple sclerosis, Parkinson's diseases or stroke and our data suggest that treatment resembles guideline recommendations.

PUK2
META-ANALYSIS OF IL-2 RECEPTOR ANTAGONIST (IL-2 RA) AS INDUCTION THERAPY IN PEDIATRIC RENAL TRANSPLANTATION
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OBJECTIVES: Therapy with interleukin-2 receptor antagonists (IL-2Ra) has resulted in significantly decreasing numbers of acute rejection episodes in adult renal transplant recipients. Acute rejection remains a major threat for graft failure resulting in increased immunosuppression and attendant comorbidities. There are limited data available regarding use of IL-2Ra in pediatric kidney recipients. This study aims to systematically identify and summarize the effects of using IL2-Ra for induction therapy in pediatric renal transplantation. **METHODS:** Databases, reference lists, and abstracts of conference proceedings were searched extensively to identify relevant RCTs from January 1991-August 2012 in all languages using following terms "kidney transplantation", "renal transplantation", "IL-2Ra". Twenty-eight trials were identified of which eight (N=893) satisfied inclusion criteria: including patients less than 19 years old; with comparison of IL-2Ra to placebo or as an addition to standard therapy or as an alternative to other antibody therapy. Key clinical events included were graft survival and acute rejection. Heterogeneity was assessed using I^2 statistic. With I^2<50%, fixed effects model was used. Results were expressed as odds ratio (OR) with 95% confidence intervals (CI) at 6 or 12 months post-transplantation. **RESULTS:** Incidence of clinically diagnosed acute rejection within one year of transplantation when patients received placebo was 35% higher than those recipients who received IL-2Ra [OR 0.74; CI (0.48, 1.20); p=0.18]. The use of an IL-2Ra in addition to standard double drug therapy or triple drug therapy significantly reduces acute rejection in the first post-transplant year [OR 0.55; CI (0.33, 0.90); p<0.05]. The odds of graft survival when patients received IL-2Ra was 88% higher in treatment compared with placebo/no treatment/ [OR 1.88; CI (1.2, 3.0); p<0.05]. **CONCLUSIONS:** IL-2Ra offers excellent allograft survival and a lower incidence of biopsy proven acute rejections. Therefore, IL2-Ra can be recommended for routine induction immunosuppressive therapy in pediatric renal transplantation.

PUK3
ISCHEMIA TIME ON RENAL ALLOGRAFT SURVIVAL: EFFICACY OF MACHINE PERFUSION
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OBJECTIVES: To evaluate the efficacy and safety of machine perfusion for human kidneys obtained from living or cadaveric donors for transplantation. **METHODS:** We searched for systematic reviews (SR) of clinical trials that compared machine perfusion and static cold storage for renal graft preservation in the Cochrane Library, Centre for Reviews and Dissemination, Medline (via Pubmed) and LILACS databases. We also searched for Health Technology Assessments (HTA) in agencies websites. The quality of the evidence and strength of recommendation were evaluated according to the GRADE system. **RESULTS:** We included eight studies: five SR and three HTA. The SR did not show statistically significant differences in graft survival, patient survival and primary non-function between static cold storage and machine perfusion groups. Patients who received grafts stored in machine perfusion showed better results regard to delayed graft function in all studies. Most SR presented poor quality of evidence, and all lead to a weak recommendation against the technology. The three HTA corresponded to recommendations of two agencies, one in favor of the machine perfusion use and the other left the choice of the storage method in discretion of the institution. **CONCLUSIONS:** Considering all the studies, as well as their limitations, there is a lack of evidence to support the nationwide use of renal machine perfusion in Brazil. Despite the absence of a substitutive technology (the standard gold is static cold storage) the studies did not indicate results that represent a gain in graft and patient survival.

PUK4
COMPARING TREATMENT MODALITIES FOR END-STAGE RENAL DISEASE: A META-ANALYSIS
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OBJECTIVES: Despite technological advances in treatment modalities for end stage renal disease (ESRD) the disease continues to impose significant economic and social burdens on patients and health care systems globally. The purpose of this review was to compare the effectiveness of transplantation (Tx) and peritoneal dialysis (PD) to the more common treatment modality, hemodialysis (HD). The outcome of interest was the health related quality of life (HRQOL) of ESRD patients in the general, physical and psychological domains. **METHODS:** The primary computerized databases searched for scholarly articles were PubMed and Medline. Only research studies written in English which met the inclusion criteria were considered. A random effects model was used to test the hypothesis of equality in mean treatment outcomes. **RESULTS:** A total of 21 studies with a combined sample size of 17,099 patients were used in the review. Patients who received PD did not have a better HRQOL compared to patients receiving HD. However, the HRQOL of Tx patients was significantly better than that of HD patients in the physical and psychological domains. The overall effect sizes were 0.31, 95 % CI (0.09, 0.53) and 0.29, 95 % CI (0.09, 0.50) respectively, and were statistically significant. **CONCLUSIONS:** The findings support the assertion that Tx patients experience significantly better HRQOL than HD patients but only in the physical and psychological domains. Findings on the effectiveness of PD compared to HD as a treatment modality were inconclusive.

PUK5
THE ECONOMIC AND HUMANISTIC BURDEN OF TREATMENT ALTERNATIVES FOR THE MANAGEMENT OF CHRONIC URINARY RETENTION IN ADULT SPINAL CORD INJURED INDIVIDUALS
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OBJECTIVES: To systematically review the literature to identify studies relating to the humanistic burden and the cost-effectiveness of treatments for chronic urinary retention (CUR) in spinal cord injured (SCI) individuals. **METHODS:** Searches were made in the following databases: MEDLINE, Medline in process, EMBASE, EconLit and the NHS Economic Evaluation Database. No year restrictions were placed on the date of publication. The eligibility criteria in both reviews were adults with CUR requiring catheterisation. Searches were restricted to full English language publications in both cases. Only full economic evaluations or studies using generic utility instruments were considered for inclusion. Abstracts were reviewed against pre-specified inclusion criteria by two of the authors, with a third providing advice in areas of disagreement. Data extraction was undertaken by two authors and validated by a third author. **RESULTS:** Following de-duplication, a total of 518 and 627 abstracts retrieved from the cost-effectiveness and utility searches respectively were reviewed for inclusion. Of these, two economic evaluations and four utility studies were included. One of the models used the Quality Adjusted Life Year (QALY) as a measure of benefit, with the Incremental Cost-Effectiveness Ratio ranging from £3,270 to £51,345 per QALY gained depending on the choice of interventions assessed. The SF-36 instrument was used in all four included utility studies. Statistically significant differences were observed for almost all domains in individuals with CUR compared to matched non-CUR individuals and HRQoL was also observed to be negatively associated with the level of incontinence (categories: no incontinence, yes monthly, yes weekly, yes daily). **CONCLUSIONS:** There is a paucity of information on both the cost-effectiveness and humanistic burden of interventions for adult CUR individuals with an SCI but what evidence there is indicated that CUR triggers a reduction in health related quality of life and that certain bladder management options are cost-effective.